

FORM PTO-1449

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Patent and Trademark Office

Atty Docket No.

P0998D1

Serial No.

## LIST OF DISCLOSURES CITED BY APPLICANT

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Applicant

Cleland et al.

Filing Date

18 Mar 1999

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1642

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 09/27/99  
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## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
<i>[Signature]</i>	* 1	08/508,014		Fick et al.	<i>[Handwritten marks]</i>	<i>[Handwritten marks]</i>	27.07.95
	* 2	4,093,606	06.06.78	Coval, M.			
	* 3	4,499,073	12.02.85	Tenold, R.			
	* 4	4,877,608	31.10.89	Lee, T. et al.			
	* 5	4,940,782	10.07.90	Rup et al.			08.06.87
	* 6	5,032,405	16.07.91	Huang, H. et al.			
	* 7	5,036,049	30.07.91	Audhya, T. et al.			
	* 8	5,096,885	17.03.92	Pearlman et al.			
	* 9	5,149,653	22.09.92	Roser			
	*10	5,215,743	01.06.93	Singh, M. et al.			
	*11	5,262,296	16.11.93	Ogawa, E. et al.			
	*12	5,399,670	21.03.95	Bhattacharya, P. et al.			
	*13	5,410,025	25.04.95	Moller et al.			18.11.93
	*14	5,514,554	07.05.96	Bacus, S.			
	*15	5,571,894	05.11.96	Wels, W. et al.			
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	*17	5,587,458	24.12.96	King, C. et al.			
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	*22	5,821,337	13.10.98	Carter et al.			

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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
<i>[Signature]</i>	*23	AU-B-30771/89	07.09.89	AUSTRALIA	<i>[Handwritten marks]</i>	<i>[Handwritten marks]</i>		
	*24	2,138,853	29.06.95	CANADA				
	*25	0 531 539 A1	17.03.93	EPO				
	*26	303,746	22.02.89	EPO				
	*27	391,444	10.10.90	EPO				
	*28	597,101	18.05.94	EPO				
	*29	661,060	05.07.95	EPO (WITH ENGLISH ABSTRACT)				
	*30	841,067	13.05.98	EPO				
	*31	84/00890	15.03.84	PCT				
	*32	WO 89/09402	05.10.89	PCT (WITH ENGLISH ABSTRACT)				
	*33	WO 89/11297	30.11.89	PCT				

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9/19/03

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8	*34	WO 90/11091	04.10.90	PCT			
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	*36	WO 93/05799	01.04.93	PCT			
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*38	"Sandoglobulin" <u>Physicians' Desk Reference</u> pps. 1965-1966 (1991)
*39	"IVEEGAM", "Product Information, IMMUNO U.S., Inc." pps. 2 pages (1992)
*40	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 14(3):737-744 (1996)
*41	Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995)
*42	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185 <sup>HER2</sup> Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (1996)
*43	Beauvais et al., "Both Glassy State and Native Structure are Required for Storage Stability of Lyophilized Interleukin-1 Receptor Antagonist" <u>Pharm. Res.</u> (Abstract #2007) 12(9):S-80 (1995)
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*48	Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993)
*49	Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995)
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*51	Izutsu et al., "The effects of additives on the stability of freeze-dried $\beta$ -galactosidase stored at elevated temperature" <u>Intl. J. Pharmaceutics</u> 71:137-146 (1991)
*52	Manning et al., "Stability of Protein Pharmaceuticals" <u>Pharm. Res.</u> 6(11):903-918 (1989)
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	*59	4,891,319	02.01.90	Roser			07.05.87
	*60	5,849,700	15.12.98	Sorensen et al.			02.06.95

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	192	5,359,046	25.10.94	Capon et al.			
	193	5,401,638	28.03.95	Carney et al.			
	194	5,578,482	26.11.96	Lippman et al.			
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	196	5,663,144	02.09.97	Greene et al.			
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	198	5,726,023	10.03.98	Cheever et al.			
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	200	5,801,005	01.09.98	Cheever et al.			
	201	5,837,243	17.11.98	Deo et al.			
	202	5,837,523	17.11.98	Greene et al.			
	203	5,846,538	08.12.98	Cheever et al.			
	204	5,869,445	09.02.99	Cheever et al.			
	205	5,876,712	02.03.99	Cheever et al.			
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	207	5,908,835	01.06.99	Bissery			
	208	5,910,486	08.01.99	Curriel et al.			
	209	5,922,845	13.07.99	Deo et al.			
	210	5,939,531	17.08.99	Wels et al.			
	211	5,977,322	02.11.99	Marks et al.			
	212	6,054,297	25.04.00	Carter et al.			
	213	6,123,939	26.09.00	Shawver et al.			

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	215	711,565	26.08.98	EPO			
	216	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)			
	217	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
	218	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	219	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	220	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	221	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
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	223	7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	224	95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
	225	WO 92/10573	25.06.92	PCT			
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	227	WO 93/21232	28.10.93	PCT			
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	229	WO 94/10202	11.05.94	PCT			
	230	WO 94/28127	08.12.94	PCT			
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	232	WO 95/17507	29.06.95	PCT			
	233	WO 95/28485	26.10.95	PCT			
	234	WO 96/18409	20.06.96	PCT			
	235	WO 96/30046	03.10.96	PCT			
	236	WO 97/27848	07.08.97	PCT			
	237	WO 97/38731	23.10.97	PCT			
	238	WO 97/45140	04.12.97	PCT			
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